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| 10/657,440 | 09/08/2003 | Kazumasa Masuda | KITO3.001AUS | 1430 |
| 20995 | 7590 | 06/22/2009 | EXAMINER | |
| KNOBBE MARTENS OLSON & BEAR LLP | | | HALL, DEANNA K | |
| 2040 MAIN STREET | | | ART UNIT | PAPER NUMBER |
| FOURTEENTH FLOOR | | | 3767 | |
| IRVINE, CA 92614 | | | | |

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|-------------------|---------------|
| NOTIFICATION DATE | DELIVERY MODE |
| 06/22/2009 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/657,440 | MASUDA ET AL. | |
| | Examiner | Art Unit | |
| | DEANNA K. HALL | 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 20 March 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2,5-8,11 and 14-17 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,2,5-8,11 and 14-17 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 08 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on March 20, 2009.
2. In the reply, the applicant amended claims 1, 5-8, 11 and canceled claims 3-4, 9-10, 12-13. Claims 1-2, 5-8, 11, 14-17 are pending in the application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1-2, 5-8, 11, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uber, III et al. (US 5,840,026) (“Uber”).**

The following claim limitations are disclosed in the aforementioned Uber patent in Figures 2, 3a and 3b, Table I, C2 L66- C3 L28 and C5 L21-C8 L62.

Uber discloses:

A liquid injection mechanism for injecting a contrast medium into a subject; pattern storing means for registering data of a variable pattern in which an injection rate of the contrast medium for keeping an image contrast of the fluoroscopic image within a predetermined range varies with time; and rate controlling means for varying an

operating speed of said liquid injection mechanism with time according to said variable pattern.

Pattern storing means comprises means for registering the data of the variable pattern in order to maintain a state in which the image contrast of the fluoroscopic image that is produced by said contrast medium approximates an optimum level.

Total amount entering means for accepting entered data of a total amount of the contrast medium to be injected into the subject; said rate controlling means comprising means for increasing or reducing said injection rate in elapsed times according to said variable pattern depending on said total amount of the contrast medium to be injected into the subject.

Data entering means for accepting entered data of the body weight of the subject; and total calculating means for increasing or reducing said total amount of the contrast medium to be injected into the subject in proportion to the body weight whose data has been entered by said data entering means.

Coefficient storing means for registering data of predetermined coefficients assigned to respective regions to be imaged of the subject; data entering means for accepting entered data of a region to be imaged of the subject; coefficient reading means for reading the data of one of the coefficients from said coefficient storing means depending on the region to be imaged of the subject whose data has been entered by said data entering means; and total calculating means for correcting said total amount of the contrast medium to be injected into the subject by multiplying said total amount by the coefficient whose data has been read by said coefficient reading means.

The contrast medium is available in a plurality of types having different concentrations of an effective component contained therein, further comprising: concentration storing means for registering data of the different concentrations in the types of said contrast medium; data entering means for accepting entered data of a type of the contrast medium; concentration reading means for reading data of the concentration from said concentration storing means depending on the type of the contrast medium whose data has been entered by said data entering means; and total calculating means for increasing or reducing said total amount of the contrast medium to be injected into the subject in inverse proportion to said concentration whose data has been read by said concentration reading means.

The contrast medium is available in a plurality of types having different concentrations of an effective component contained therein, further comprising: concentration storing means for registering data of the different concentrations in the types of said contrast medium; coefficient storing means for registering data of predetermined coefficients assigned to respective regions to be imaged of the subject; data entering means for accepting entered data of at least the body weight of the subject, a region to be imaged of the subject, and one of the types of the contrast medium; concentration reading means for reading data of the concentration from said concentration storing means depending on the type of the contrast medium whose data has been entered by said data entering means; coefficient reading means for reading the data of one of the coefficients from said coefficient storing means depending on the region to be imaged of the subject whose data has been entered by said data entering

means; and total calculating means for correcting said total amount of the contrast medium to be injected into the subject, which has been increased or reduced in proportion to said body weight and in inverse proportion to said concentration, by multiplying said total amount by said one of the coefficients.

Uber further discloses varying an injection rate of said contrast medium with time according to said variable pattern.

Accepting entered data of a total amount of the contrast medium to be injected into the subject; and increasing or reducing said injection rate in elapsed times according to said variable pattern depending on said total amount of the contrast medium to be injected into the subject.

Registering data of the different concentrations in the types of said contrast medium; registering data of predetermined coefficients assigned to respective regions to be imaged of the subject; accepting entered data of at least the body weight of the subject, a region to be imaged of the subject, and one of the types of the contrast medium; reading data of the concentration depending on the type of the contrast medium whose data has been entered; reading the data of one of the coefficients depending on the region to be imaged of the subject whose data has been entered; and correcting said total amount of the contrast medium to be injected into the subject, which has been increased or reduced in proportion to said body weight and in inverse proportion to said concentration, by multiplying said total amount by said one of the coefficients.

Uber further discloses a computer unit comprising: pattern storing means for

registering data of a variable pattern in which an injection rate of the contrast medium varies with time; and rate controlling means for varying an operating speed of said liquid injection mechanism with time according to said variable pattern.

Total amount entering means for accepting entered data of a total amount of the contrast medium to be injected into the subject; said rate controlling means comprising means for increasing or reducing said injection rate in elapsed times according to said variable pattern depending on said total amount of the contrast medium to be injected into the subject.

Concentration storing means for registering data of the different concentrations in the types of said contract medium; coefficient storing means for registering data of predetermined coefficients assigned to respective regions to be imaged of the subject; data entering means for accepting entered data of at least the body weight of the subject, a region to be imaged of the subject, and one of the types of the contrast medium; concentration reading means for reading data of the concentration from said concentration storing means depending on the type of the contrast medium whose data has been entered by said data entering means; coefficient reading means for reading the data of one of the coefficients from said coefficient storing means depending on the region to be imaged of the subject whose data has been entered by said data entering means; and total calculating means for correcting said total amount of the contrast medium to be injected into the subject, which has been increased or reduced in proportion to said body weight and in inverse proportion to said concentration, by multiplying said total amount by said one of the coefficients.

The computer program to carry out a process of varying an operating speed of said liquid injection mechanism with time according to said variable pattern.

The computer program accepting entered data of a total amount of the contrast medium to be injected into the subject; and Increasing or reducing said injection rate in elapsed times according to said variable pattern depending on said total amount of the contrast medium to be injected into the subject.

Enabling said computer to carry out a process comprising the steps of: registering data of the different concentrations in the types of said contract medium; registering data of predetermined coefficients assigned to respective regions to be imaged of the subject; accepting entered data of at least the body weight of the subject, a region to be imaged of the subject, and one of the types of the contrast medium; reading data of the concentration depending on the type of the contrast medium whose data has been entered; reading the data of one of the coefficients depending on the region to be imaged of the subject whose data has been entered; and correcting said total amount of the contrast medium to be injected into the subject, which has been increased or reduced in proportion to said body weight and in inverse proportion to said concentration, by multiplying said total amount by said one of the coefficients.

An information storage medium storing therein a computer program which is to be read by a computer unit.

Further, the disclosure of Uber would make the claimed specific pattern of the injection rate recited in claims 1, 8 and 11 obvious to try. "When there is a design need or market pressure to solve a problem and there are a finite number of identified,

predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.” *KSR International Co., v. Teleflex Inc. et al.* 127 U.S. 1727, 1742(2007). Further, the initial linear decrease of the injection rate up to a set point of time followed by a constant or a linear increase of the injection rate of the contrast medium is obvious to try in order to achieve decrease waste and cost while increasing efficiency, Uber C1 L4-13.

In addition, the specific pattern of the injection rate recited in claims 1, 8 and 11 is considered optimization through routine experimentation of a result-effective variable. “Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Further, “a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In Uber, the particular injection profile selected by the system is designed to provide the best image quality for the particular patient C3 L25-28. Thus, Uber is optimizing the result-effective variable, image quality (CT value). An electronic interface 56, not merely subjective personal satisfaction of the user, allows for automatic adjustment of the system C6 L29-31. Therefore, the determination of the

optimum ranges for the injection pattern based on the image quality are properly characterized as obvious subject matter characterized by routine experimentation by those of ordinary skill in the art.

Response to Arguments

5. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that the specific injection pattern is not merely optimization through routine experimentation and that the claimed injector modifies a waveform of the variable pattern vertically with the injection time unchanged. This argument is not persuasive. Uber, throughout the specification discloses the system as adjusting the concentration of the contrast media or the flow rate to provide a desirable image C11 L59-67. No where in the specification does Uber disclose or even suggest altering the injection time as a whole. Extending the injection time as a whole would cause discomfort to the patient, thus, as in Uber other means such as adjusting concentrations or flow rates, are utilized to provide the best image quality. Thus, the examiner maintains that by experimentation and optimization as discussed above, the waveform or the variable pattern is vertically moved with the injection time unchanged as the amended claims recite.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEANNA K. HALL whose telephone number is (571)272-2819. The examiner can normally be reached on M-F 9:00am-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deanna K. Hall/
Examiner, Art Unit 3767
6/17/09

/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767